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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,867	09/13/1999	DAVID A. WILLIAMS	7037-377/IU-	5039

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EXAMINER
NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/394,867	WILLIAMS, DAVID A.	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-23,38-43 and 79-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-23,38-43 and 79-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 September 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

In view of the entered and accepted petition dated Jan 30, 2004, and a request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), filed in this application after final rejection, this application is eligible for continued examination under 37 CFR 1.114. Since the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2004 has been entered.

Claim 38 and 83 have been amended by the amendment dated Jan 30, 2004

Elected claims 11-23, 38-43 and 79-83, to which the following grounds of rejection remain and/or are applicable, are pending.

The drawings remain objected in view of the reasons set forth in the PTO-948 attached to the previously sent office action. In order to facilitate the publication of a patent should this application be issued as a US patent, Correction of the drawings before the notice of allowance is suggested.

Applicant's response and claim amendment have removed the rejections under 35 USC 112, first paragraph.

The request to correct inventorship (37 CFR 1.48(c)), dated Jan 30, 2004, has been considered and entered without any finding of any deceptive intention in the making of the inventorship error. As such, -- Wikram P. Patel -- has been added as the second inventor of this instant application.

As the result of the inventorship's change, the examiner notes that this application, while being a continuation of the parent 08/536,891, now US Pat No. 6,033,907, does not have the same inventive entity as that of the '907 patent, and has in fact one common assignee. Thus,

double patenting remains between the '907 patent and this application, which is filed by an inventive entity having a common inventor with the patent, and/or by the owner of the patent.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-23, 38-43, 79-83 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of US Pat No. 6.033.907.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the two sets of claims are readable on

A method for obtaining a transduced population of viable mammalian cells by a retrovirus expressing ADA, a composition containing the transduced populations, and a method of enhancing the transduction of retrovirus vectors into hematopoietic cells, wherein all of the methods and compositions require the presence of substantially pure fibronectin, substantially pure fibronectin fragments, or a mixture thereof, so as to increase the frequency of transduction of the hematopoietic cells by the retrovirus vector.

Thus, given that the patent claims are not patentably distinct from that of the examined claims, and that the patent claims embrace the above claimed subject matter, the examined claims are obvious variants of that claimed in the patent.

Applicant's response dated January 30, 2004, particularly page 8 bridging page 9, has been considered by the examiner but is not found persuasive. Applicant mainly argues that since the '907 patent is not commonly owned with the present application, no double patenting issue exists. The argument is not found persuasive because insofar as the '907 patent and this application are both filed by an inventive entity having a common inventor with the patent, and/or by the owner of the patent, double patenting issue remains, particularly since the examined claims are generic to that of the patent claims, and thus, are obvious variants of the claimed subject matter in the issued patent. Accordingly, since the inventor/patent owner has already secured the issuance of a first patent, the examiner must determine whether the grant of a second patent would give rise to an unjustified extension of the rights granted in the first patent. In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is — does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? Given the immediately preceding paragraphs, the answer is yes, and thus, an "obviousness-type" nonstatutory double patenting rejection is appropriate. The examiner acknowledges that while the claims in the issued patent do not exactly have the same scope as that of the examined claims, the patent claims are clearly drawn a species embraced by the scope of the examined claims, and that both does have the same disclosure. Thus, obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See

Eli Lilly & Co. v.Barr Labs., Inc., 251 F.3d 955, 58 USPQ2d 1865 (Fed. Cir. 2001); Ex parte Davis, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).

35 USC 102(f)
A person shall be entitled to a patent unless –
(f) he did not himself invent the subject matter sought to be patented.

Given that inventorship of the '907 patent is "TO ANOTHER" where there are distinct inventive entity with one inventor (David A. Williams) in common, and that the claimed subject matter and the subject matter claimed in the issued patent were not, at the time invention was made, owned by the same person or subject to an obligation of assignment to the same person, a rejection under 35 USC 102(f)/103 is set forth below:

Claims 11-23, 38-43, 79-83 are rejected under 35 USC 102(f)/103 as being unaptentable over the claims 1-14 of US Pat No. 6.033.907.

Both the examined claims and the patent claims are drawn to

A method for obtaining a transduced population of viable mammalian cells by a retrovirus expressing ADA, a composition containing the transduced populations, and a method of enhancing the transduction of retrovirus vectors into hematopoietic cells, wherein all of the methods and compositions require the presence of substantially pure fibronectin, substantially pure fibronectin fragments, or a mixture thereof, so as to increase the frequency of transduction of the hematopoietic cells by the retrovirus vector.

Thus, given that both disclosures are identical, and that the examined claims are derived from that of the patent claims, which is issued to "AN ANOTHER", the rejection under 35 USC 102(f)/103 is proper. Applicant's response, particularly page 8 and page 9, does not provide any evidence the patent claims do not embrace the claimed subject matter of the examined claims. A mere fact that the patent claims are explicitly directed to a particular species, where polybrene is not employed, does not preclude the fact that both set of claims embrace the same

claimed subject matter. As such, a change of inventorship in this application does lead to a reasonable conclusion that the claimed subject matter in this instant application is derived from that of the patent claims, where the patent has a distinct inventive entity, as explained above.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0804.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

D NGUYEN
PRIMARY EXAMINER